ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

Location of Meeting
Frontier Building, 3601 C Street, Room 890/896

FINAL - MINUTES OF MEETING
September 16, 2011
8:00 a.m.

Committee Members Present:
Marvin Bergeson, MD
Amber L. Briggs, Pharm.D.
Richard Brodsky, MD
Robert H. Carlson, MD
Mary Elizabeth Gardner, ANP
Vincent Greear, R.Ph.
Daniel P. Kiley, DDS MPH
Diane Liljegren, MD (telephonic)
William McCormick, Pharm.D.
John Pappenheim, MD
Claudia Phillips, MD
John Riley, PA
Trish White, R.Ph. (telephonic)

Committee Members Absent:
Dharma Begich, Pharm.D.
Jeffrey Demain, MD
Paul Michaud, Pharm.D.
Jill Reid, R.Ph.
Alex Malter, MD MPH

Others Present:
Chad Hope, Pharm.D.
Julie A. Pritchard, Pharm.D.
Flora Solomon

Before the meeting was called to order, Mr. Hope announced that Mr. Campana had retired and would no longer be participating in the Alaska Medicaid Pharmacy and Therapeutics Committee.

1. Call to Order – Chair

Chair Brodsky called the meeting to order at 8:00 a.m.

2. Roll Call

A quorum was present.

3. Public Comments - Local Public/Health Practitioners

There were no public comments.

4. Review of Topical Antiviral Medications for HSV (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Topical Antiviral Medications for HSV. These products are used for cold sores occurring from either an HSV-1 or HSV-2 infection. Recurrences resulting from HSV-2 are rare, but about 80 percent of the adult population is infected with HSV-1. Abreva is the only FDA approved over the counter medication, but the mechanism of action is unknown. Systemic absorption of a topical antiviral is low. Topical therapy should be started during the prodomal period and used for acute outbreaks only. Xerese, a combination product of Acyclovir and Hydrocortisone, is also available for treatment of cold sores for those 12 years and older. It is applied five times a day for five days. In August, there were 31 claims: 48% for Zovirax crème, 38% for Zovirax ointment, and 13% for Denavir. At the last review, a motion for class effect passed unanimously.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

5. Re-Review of Electrolyte Depleters (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Electrolyte Depleters. The various drugs in the category were reviewed. Lanthanum is contraindicated in bowel obstruction, ileus and fecal impaction. The tablet should be chewed thoroughly to reduce the risk of GI events. All agents are FDA approved for the treatment of elevated phosphate levels in renal disease. Although Renagel and Renvela have similar adverse event profiles, it was noted that Renvela had a slightly higher incidence of upper GI events. In August, there were 78 claims: 52% for Renvela, 40% for Calcium Acetate, 8% for Renagel. At the last review, a motion for therapeutic alternatives passed unanimously. Significant changes include that Phoslyra became available. It is indicated to reduce serum phosphorous in patients with end-stage renal disease. Although there have been no clinical trials with the intended population, it is anticipated that Phoslyra will have adverse events similar to the gel caps and tablet formulations.

DR. GREEAR MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

6. Re-Review of Anticoagulants (formerly LMW Heparins) (Red Category)

LAURA LITZENBERGER: A representative of Janssen Scientific Affairs discussed Xarelto (Rivaroxaban). Xarelto is a new oral anticoagulant that is indicated for the prevention of DVT, which may lead to PE after hip and knee replacement surgery. Xarelto is a direct 10-A inhibitor. Since this drug is oral 10-A inhibitor and has predictable pharmacokinetics and pharmcodynamics, there is no need for any anticoagulation monitoring. Four clinical trials and their outcomes were reviewed. Xarelto was approved in July and it beginning to be added to the formularies in Alaska.

In response to Dr. Briggs, Ms. Litzenberger said she did not have the exact percentage of increased risk when Xarelto and CYP3A4s were given simultaneously. However, the recommendation is to avoid drugs that have a strong 3A4 inhibitor and a substrate of peclyp protein. If a product is a moderate 3A4 inhibitor and a substrate of peclyp protein and patient has a moderate decrease in renal function then the patient may have a higher risk of bleeding and the benefits/risk profile should be considered. In the clinical trials, the dose was not reduced for normal aging renal dysfunction. Xarelto is not indicated for

patients with a creatic clearance of less than 30. Any anticoagulant combined with an anti-platelet agent may cause an increased risk of bleeding.

In response to Dr. Hope, Ms. Litzenberger said Xarelto should be started within 6 to 10 hours after surgery. The atrial fibrillation indication, which would be a different dose, is pending at the FDA.

Dr. Pritchard gave the Magellen presentation on LMW Heparins. The injectable and oral products in the class were reviewed. The injectable agents are not considered interchangeable. Oral agents are preferred for long-term anticoagulation, except for Xaltero, which is only used for a specific number of days. In August, there were 63 claims for the oral products: 51% for Lovenox, 45% for Enoxaparin, and 4% for Arixtra. There were 47 claims for the injectable products: 100% claims for Pradaxa. At the last review, a motion for therapeutic alternatives passed unanimously. The significant changes are that Pradaxa and Xaltero became available. Pradaxa and Xaltero, both oral agents, were reviewed.

DR. KILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

7. Review of MS Drugs (Red Category)

MELISSA WALSH: A representative of Novartis discussed Gilenya (Fingolimod). Gilenya is the first oral disease modifying therapy indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. It is dosed as .5 milligrams orally, once daily, and is a first line choice for patients with MS. Gilenya is a first in class agent, known as S1P receptor modulators. It has been evaluated in the largest phase-three clinical trial program conducted to date in MS, which includes two key studies that were both published in the New England Journal of Medicine. The studies and their outcomes were reviewed. Gilenya has a well-studied efficacy and safety profile, which has been characterized in more than 2,600 clinical trial patients. It has been approved in the U.S. with a REMS designed to inform patients and providers on the safe use and serious risks of Gilenya. The approved REMS includes a medication guide for patients, and a letter and safety information guide for healthcare providers. For full prescribing information, go to www.gilenya.com. Gilenya should be considered for inclusion on the PDL.

In response to Dr. Briggs, Ms. Walsh said the recommendation was that the first dose be given in a first dose observation site where patients can be observed for six hours. Dr. Hope noted that Gilenya was an oral medication, but it is a disease modifying therapy.

ELAINE THOMAS: A representative of Bayer Biologic discussed Betaseron. It was the first approved disease modifying therapy for MS. It has the longest safety record with 700,000 patient years of experience. Since last year, there have been several studies done including the START study and the BEYOND study, which were reviewed. An analysis of the PIVOTAL trial group was done after 21 years and showed that early treatment with Betaseron in the PIVOTAL trial was associated with a change in the survival probability. Using the intention-to-treat principal and looking at the original assignment of different groups, they found 98.4% of those original trial patients, 22% per were dead and 78% were alive. The primary end-point of the 21-year study was to look at survival versus all-cause mortality and they found that there was a significant reduction in all-cause mortality and the risk

of death was reduced by 47% for patients originally randomized to Betaseron versus those randomized to placebo. Betaseron has a small needle and does not need to be refrigerated. We believe that all MS drugs should be included on the PDL.

Dr. Pritchard gave the Magellen presentation on MS drugs. Copaxone, which is not an interferon, and interferon beta are immunoregulatory agents that reduce relapse rates and slow progression of disease. Avonex is administered IM. The others in this group are sub-Q. Ampyra, an oral agent, is a broad-spectrum potassium channel blocker indicated to improve walking as demonstrated by an increase in walking speed. It is not considered a treatment. Contraindications for Ampyra are moderate to severe renal impairment. The Interferon Beta-1a includes Avonex and Rebif. The Interferon Beta-1b includes Betaseron and Extavia. Gilenya and Ampyra both require medication guides at time of dispensing. In August, there were 22 claims: 36% for Rebif, 32% for Copaxone, 13% for Avonex, and 9% each for Betaseron and Gilenya. At the last review, a motion for therapeutic alternatives passed with five opposed and one abstaining. The significant change is that Gilenya became available. Gilenya's exact mechanism of action is unknown. It is an oral medication. There are no contraindications to the use of this drug. The first dose can result in a decrease in heart rate and AV conduction. It is usually asymptomatic, but the patient should be observed for six hours after first administration. Due to the drug's effect on lympasites, the patient may be at a higher risk for infection. A baseline CBC is recommended, as is an ophthalmic exam as macular edema can occur. Live vaccines should be avoided during treatment and for two months after discontinuation of therapy. Gilenya is a 0.5-milligram capsule that is taken once daily.

In response to Dr. Kiley, Dr. Pappenheim said that last year there was discord regarding Ampyra, because it has a completely different mechanism of action and is meant to address the issue of ambulation as opposed to the disease process itself. The committee discussed the possibility of Ampyra being considered separately.

DR. CARLSON MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PAPPENHEIM.

Dr. Hope noted that prior authorization was required for Ampyra. Dr. Briggs suggested changing the motion to therapeutic alternatives including at least one drug besides Ampyra.

THE MOTION PASSED WITH ONE OPPOSED.

8. Re-Review of Platelet Inhibitors (Red Category)

JAMIE HURST: A representative of AstraZeneca discussed Brilinta (Ticagrelor). It is a $P2Y_{12}$ platelet inhibitor indicated to reduce the thrombotic cardiovascular events in patients with acute coronary syndromes, including unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction when given with maintenance doses of aspirin, less than 100 milligrams. Brilinta has been shown to reduce the rate of combined end-point of cardiovascular death, myocardial infarctions, or strokes when compared to Clopidogrel. In patients treated with PCI, Brilinta also reduces the rate of thrombosis. It is contraindicated in patients with a history of intracranial hemorrhage, active pathological bleeding or severe hepatic impairment. Several trials and their outcomes were reviewed. Brilinta has a boxed warning for the increased risk of bleeding, stating it should be used with maintenance doses of aspirin, less than 100 milligrams per day. Do not start

patients on Brilinta who intend to go urgent CABG surgery. When possible, discontinue Brilinta at least five days prior to any surgery. Please refer to the prescribing information for complete product information including boxed warnings and warnings for cautions.

DAN JAMES: A representative of Bristol-Myers Squibb discussed Plavix (Clopidogrel). Clopidogrel is the only drug in this class indicated for ACS, stroke, and peripheral arterial disease. It will also be available as a generic in May 2012.

Dr. Pritchard gave the Magellen presentation on Platelet Inhibitors. Indication and mechanism of action vary in this class, but the primary role is the prevention of thrombotic events. The national guidelines for stroke, unstable angina, ST-segment and non-ST-segment elevation, myocardial infarction in post-stint placement all recommend antiplatelet therapy. In October 2010, the FDA reiterated its warning of using Clopidogrel in combination with Omeprazole, saying that co-administration can result in decreased antiplatelet activity. In November of 2010, the American College of Cardiology Foundation and the American College of Gastroenterology consensus statement was updated to advise that PPIs are appropriate for those with risk of GI bleed who also require antiplatelet therapy. The use benefits should outweigh the risk of CV and GI events. Brilinta, Effient, and Plavix are all in the REMS program and medication guides are to be dispensed with all of these agents. In August, there were 356 claims: 91% for Plavix, 5% for Aggrenox, and 4% for Effient. At the last review, a motion for therapeutic alternatives with either Clopidogrel or Prasugrel being preferentially included passed unanimously. The significant change is Brilinta became available in July of 2011 as a 90-milligram tablet.

In response to Dr. Kiley, Dr. Hope said last year the committee asked that at least Plavix or Effient be included on the PDL, because of the risk of having just Aggrenox or Dipyridamole on the PDL.

DR. KILEY MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, PREFERENTIALLY INCLUDING EITHER CLOPIDOGREL OR PRASUGREL ON THE PDL. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Hematopoietic Agents (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation Hematopoietic Agents. Erythropoiesis Stimulating Agents, or ESAs, are indicated for use in patients with anemia from chronic renal failure or anemia resulting from chemotherapy for palliative intent only, not when the anticipated outcome is cure. These agents should be discontinued when chemotherapy is completed or if there is less than a one-to-two gram per desolater increase in hemoglobin. Non-responders should be checked for tumor progression, iron deficiency, or other etiologies for anemia. All ESAs are equivalent in regards to efficacy and safety. Epogen and Procrit can be used in pediatric patients and are also indicated for use in those patients with zidovudine therapy induced anemia. In August, there were 15 claims: 80% for Procrit, 13% for Aranesp, and 7% for Epogen. At the last review, a motion for class effect passed unanimously. Significant changes are that prescribers in hospitals must enroll in, and comply with, ESA APRISE Oncology Program to prescribe or dispense these agents to patients with cancer.

Dr. Hope pointed out that the FDA recently changed the hemoglobin recommendation to 10 to 12 instead of 11 to 13.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. PAPPENHEIM.

In response to Dr. Bergeson's, Dr. Hope said there was no prior authorization required for anyone through the outpatient point of sale system. One could be added, but it would not be limited to children and would be across the board. Dr. Briggs pointed out that physicians had to comply with the REMS Program.

THE MOTION PASSED UNANIMOUSLY.

10. Re-Review of Other Lipotropic Drugs (Blue Category)

ANNIE OGOSTALICK: A representative Abbott discussed Niaspan (Niacin ER). The committee is encouraged to review the full PI for comprehensive safety and efficacy data. Trials using statins to lower LDL cholesterol have shown reductions in major CV events. However, despite LDL lowering, residual CV risks remain, some of which may be modifiable. Niaspan is an extended release formulation of Niacin, which is currently the once daily prescription Niacin approved by the FDA. Niaspan's indications were reviewed. It may be used in combination with a statin and also offers an alternative to patients who may not tolerate statins. Niaspan is generally well tolerated. Flushing is the most commonly reported adverse event and led to discontinuation of fewer than 6% of patients in pivotal studies. The rate and severity of flushing is lower with Niaspan than with any immediate release Niacin. A new study called AIM HIGH, which has not yet been published, but has been widely discussed, was reviewed. The study was designed to test whether adding Niaspan to a statin would provide an additional 25% reduction in cardiovascular events. The interim results of the trial were released on May 20, 2011, and indicated that the trial would be unable to show a significant difference in cardiovascular outcome rates between the two arms. While rates were low, there appeared to be more ischemic strokes in the Niaspan arm. The DSMB recommended study cessation due to lack of incremental benefits of CV risk reduction. It is important to note that these findings were relevant for patients with stable, non-acute cardiovascular disease and well controlled LDL-C. Relevance of the results to patients outside the study population is unknown at this time. Complete data from the study needs to be analyzed, including secondary end-points and drug dosing information. Previous studies with Niaspan have not suggested an increased risk of stroke. In fact, several outcome studies have shown decreased risk in stroke. The timing of the stroke with respect to drug discontinuation, the unknown of what other lipid and other non-lipid medications the patients were taking, and the inconsistency with prior clinical studies suggest further analysis is needed. In summary, Niaspan is indicated for reducing recurrent MIs, modifying multiple lipid parameters, and continues to be an important alternative for cardiovascular protection. We respectfully urge the committee to maintain the status of Niaspan on the PDL.

Dr. Pritchard read two letters from community prescribers. Mark Swircenski's letter requested that Tricor, Trilipix, Niaspan, and Simcor be retained on the PDL for the treatment of hyperlipidemia. Ross Tanner's letter spoke against removing Niaspan from the PDL.

Dr. Pritchard gave the Magellen presentation on Other Lipotropic Drugs. This class includes Niacin, Omega-3 Fatty Acids, Cholesterol Absorption Inhibitors, Fibric Acids and Bile Acid Sequestrants.

Clinical studies have repeatedly shown that high levels of LDL is a major risk factor for coronary heart disease. Lowering these levels reduces the risk. Although accomplished by different mechanisms of action, a common goal of these agents is to lower the serum LDL. The 2011 recommendations for fasting triglycerides and LDL were reviewed. In August, claims for the bio-acid sequestant were 30% for Cholestyramine, 26% for Colestipol tablets, 22% for Triglide, 13% for Colestid tablet, and 5% or less for the rest in the class. For the triglyceride lowering agents there were 174 claims: 36% for Tricor, 33% for Lovaza, 18.5% for Gemfibrozil, and less than 10% for the rest. For the Niacin derivatives, 100% of the claims were for Niaspan. For cholesterol absorption inhibitors, 100% of the claims were for Zetia. At the last review, a motion to declare the Fibric Acids, Omega-3 Fatty Acids, and Bile Acid Sequestrants therapeutic alternatives passed unanimously. A motion to declare Niacin a class effect passed unanimously. A motion to declare Zetia a class effect passed unanimously. A motion to declare Bio-Acid Sequestrants a class effect passed unanimously. Significant changes include the AIM HIGH study, which was discussed earlier. Niaspan is the only prescription product and is an alternative for those patients who cannot tolerate statins. Substituting OTC Niacin for the prescription product is discouraged. Simcor was found to be superior to Simvastatin alone in lowering triglycerides and raising HDL. Because of their mechanism of action, Bile Acid Sequestrants have the potential for significant drug interactions.

In response to Dr. Brodsky, Dr. Pritchard said last year each of the drugs were in separate classes, but they year they are combined into Lipotropics, Other.

DR. BERGESON MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. GARDNER.

Dr. Hope noted that Niaspan has been added to the Drug Utilization Review Committee's agenda this afternoon to discuss whether it would be appropriate to send an educational letter to physicians regarding the AIM HIGH results. Dr. Carlson felt it was uncomfortable to group all of these drugs together, particularly the drugs that do not show any change in mortality. Dr. Briggs felt a drug from each group was needed on the PDL, but it probably would not happen with them grouped together.

DR. BERGESON AMENDED THE MOTION TO STATE THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, PREFERENTIALLY INCLUDING ONE DRUG FROM EACH CLASS. THE SECOND CONCURRED. THE MOTION PASSED WITH FOUR OPPOSED.

11. Re-review of Bisphosphonates (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Bisphosphonates. This category Bisphosphonates, Calcitonins, and others, which were reviewed. All are indicated for the treatment of osteoporosis in postmenopausal women, except Etidronate is indicated for the treatment of Paget's disease of the bone. The 2010 American Association of Clinical Endocrinologists guidelines state that Alendronate, Risedronate, Zoledronic Acid, or Denosumba be used as first-line agents; Ibandronate as a second-line agent; Raloxifene as a second- or third-line agent; and Calcitonin as the last-line agent for those with postmenopausal osteoporosis. In August, there were 245 claims. For the Bisphosphonates: 76% for Alendronate, 12% for Fosamax +D, and the rest were all less than 10%. For Calcitonins: 50% for

Calcitonin-Salmon nasal, 30% for Fortical, and 20% for Miacalcin. At the last review, a motion to declare the Bisphosphonates a class effect passed unanimously, and another motion to declare the Calcitonins a class effect passed unanimously. Significant changes are that Atelvia, which is Risedronate delayed release, became available for the treatment of osteoporosis in postmenopausal women. It is taken as a 35-milligram tablet immediately after breakfast, once weekly.

In response to Dr. Briggs, Dr. Pritchard said the Bisphosphonates would be for oral tablets only.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

12. Re-review of Prostate Drugs (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Prostate Drugs. The drugs in the class were reviewed. All agents show similar efficacy. Flomax, Uroxatral, and Rapaflo are Alpha 1-a selective and may have a slightly more attractive ADR profile. Jalyn is a combination of Tamsulosin and Dutasteride and the adverse reactions, warnings, and contraindications are the same as the individual products. In August, there were 412 claims. For the Alpha-Blockers, there were 306 claims: 59% for Tamsulosin, 26% for Doxazosin, and less than 10% for the others. For the 5-Alpha Reductase Inhibitors, there were 106 claims: 55% for Avodart, 41% for Finasteride, and 5% for Jalyn. At the last review, a motion to declare the Alpha-Adrenergic Blockers a class effect, to include at least one Alpha 1-A selective, passed unanimously. A second motion to declare the 5-Alpha Reductase Inhibitors a class effect passed unanimously.

In response to a question about whether this was now a single class, Dr. Hope pointed out that Magellen packaged the classifications a little differently than in prior years. In addition, Mr. Campana, who knew the history of how the classes had been broken out in the past, did not set this agenda.

DR. PAPPENHEIM MOVED A CLASS EFFECT FOR THE 5-ALPHA REDUCTASE INHIBITORS, AND A CLASS EFFECT FOR THE ALPHA-ADRENERGIC BLOCKERS TO INCLUDE AT LEAST ONE ALPHA 1-A SELECTIVE AGENT. SECONDED BY DR. GREEAR. THE MOTION PASSED WITH ONE OPPOSED.

Break from 9:15 a.m. to 9:38 a.m.

13. Re-review Calcitonins (Green Category)

Dr. Pritchard gave the Magellen presentation on Calcitonins. In August, there were 10 claims, which were divided between Calcitonin-Salmon, Fortical, and Miacalcin. At the last review, a motion for class effect passed unanimously.

DR. PAPPENHEIM MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

14. Re-review of Alzheimer's Drugs (Green Category)

Dr. Pritchard gave the Magellen presentation on Alzheimer's Drugs. Namenda has a unique mechanism of action. It is an NMDA receptor antagonist. Blockade of this major glutamate receptor may prevent neuronal death resulting from excess glutamate release. Exelon patches have had several medication errors resulting from not removing the old patch or applying multiple patches at one time. Patients and caregivers need to be educated on proper dosage and administration of the patch. In August, there were 86 claims: 49 claims for Namenda. At the last review, a motion for therapeutic alternatives passed unanimously. The only change is that Tacrine (Cognex) is no longer available.

The committee discussed the Exelon patch. The patch should be changed daily.

DR. PAPPENHEIM MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. KILEY.

Dr. Briggs spoke against the motion and felt one drug from each class should be included in the motion.

DR. PAPPENHEIM AMENDED THE MOTION TO DECLARE THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE ONE DRUG FROM EACH GROUP. THE SECOND CONCURRED. THE MOTION PASSED UNANIMOUSLY.

15. Re-review of Oral Agents for Gout, Xanthines, Miscellaneous (Green Category)

Dr. Pritchard gave the Magellen presentation on Oral Agents for Gout, Xanthines, and Miscellaneous. Colcrys is the only FDA approved branded Colchicine. It is indicated for both the treatment and prevention of gout flares. Gout is managed in three stages, which are acute treatment, prophylaxis to prevent acute flares, and lowering excess stores of urate to prevent flares of gouty arthritis and prevent tissue deposition of urate crystals. In August, there were 286 claims: 81% for Allopurinol, 14% for Colcrys, and 5% for Uloric. At the last review, a motion for therapeutic alternatives passed unanimously. Significant changes include Xanthine oxidase inhibitor therapy should not be initiated until four to six weeks after an acute episode. For patients already on Uloric or Allopurinol, do not stop the therapy. After starting Uloric, an increase in gout flares is common due to mobilization of urate from tissues, and concurrent treatment with NSAIDS or Colchicine is recommended for up to six months.

In response to Dr. Riley, Dr. Pritchard said this class was not previously on the PDL so there were no preferred products at this time.

DR. RILEY MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, PREFERENTIALLY INCLUDING A XANTHINE OXIDASE INHIBITOR AND A URIC SERIC. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

16. Re-review of Parkinson Drugs (Green Category)

Dr. Pritchard gave the Magellen presentation on Parkinson Drugs. Parkinson's disease is a progressive, neurodegenerative disorder with main features of tremor, bradykinesia, and rigidity. Parkinson's is characterized by striatal dopamine deficiency and dopamine agonists are used as therapy in early Parkinson's. They have a Levodopa sparing effect and can reduce the frequency of off time. In August, there were 205 claims: 50% for Pramipexole, 45% for Ropinirole, and less than 5% for Mirapex and Requip. At the last review, a motion for class effect passed unanimously. New information is that the FDA is evaluating findings that Levodopa, Carbidopa, and Entacapone may be associated with an increased risk of cardiovascular events.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

17. Re-review of Endothelin Receptor Agonists (Green Category)

Dr. Pritchard gave the Magellen presentation on Endothelin Receptor Antagonists. This class is also known as the PAH agents. There are two unique oral endothelin receptor agonists in this class. They are both indicated for the treatment of PAH. Tracleer is indicated for Class 2, 3 and 4. Letairis is indicated for Class 2 and 3. Endothelin receptor subtype specificity is different between agents. Drug selection is complex depending on many factors. The other therapies, which are not being reviewed, were briefly discussed. In August, there were 5 claims: 3 for Tracleer and 2 for Letairis At the last review, a motion for therapeutic alternatives passed unanimously. The significant change is that the boxed warning for potential liver injury with Letairis was removed. Monthly LFT monitoring is no longer required. Letairis and Tracleer are both part of the REMS program.

DR. BRIGGS MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

18. Re-review of New Agents for Angina (Green Category)

Dr. Pritchard gave the Magellen presentation on New Agents for Angina. The only drug in this class is Ranexa (Ranolazine). It has a first-line chronic angina indication. It may reduce HBA1C in those patients with coronary artery disease and diabetes. However, it is not used to treat diabetes alone. In August, there were no claims. At the last review, a motion for class effect passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

19. Re-review of Bile Acid Salts (Green Category)

Dr. Pritchard gave the Magellen presentation on Bile Acid Salts. These agents are used to dissolve gallstones as an alternative to cholecystectomy. Not every patient experiences complete dissolution of stones and recurrence has been observed in almost 50% of patients within five years of bile acid therapy. In August, there were 63 claims: 100% for Ursodiol. At the last review, a motion for therapeutic alternatives passed unanimously.

The committee discussed the difference between class effect and therapeutic alternatives.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

20. Re-review of Pancreatic Enzymes (Green Category)

Dr. Pritchard gave the Magellen presentation on Pancreatic Enzymes. These agents differ in enzyme content and bioavailability. They all demonstrate favorable risk benefit profiles in treatment of pancreatic insufficiency due to cystic fibrosis and other conditions like chronic pancreatitis. In August, there were 76 claims: 46% for Creon DR, 42% for Zenpep, 8% for Pancrelipase, and 4% for Pancreaze. At the last review, a motion for therapeutic alternatives passed unanimously. The only change is that Creon came out with a new strength this summer.

In response to Dr. Briggs, Dr. Hope said that there used to be a lot of generics, but they were not FDA approved. The company went back and got them approved by the FDA so now they are available as brand-name products only.

DR. BRIGGS MOVED THAT THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

21. Re-review of Topical Agents for Psoriasis (Green Category)

Dr. Pritchard gave the Magellen presentation on Topical Agents for Psoriasis. Psoriasis is a chronic autoimmune disease that appears on the skin, but it can also affect the joints and connective tissue. Topical corticosteroids are the cornerstone of treatment. These agents have different mechanisms of action, but the effect is the normalize the skin cell production and reduce inflammation. In August, there were 11 claims: 45% for Dovonex ointment, 45% for Vectical, and 9% for Taclonex. At the last review, a motion for class effect passed unanimously. The change is that Taclonex should not be used in patients with calcium metabolism disorders. Hypocalcaemia and hypercalciuria have occurred in patients using Taclonex.

DR. KILEY MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

22. Re-review of Cytokine and CAM Agonists (formerly Anti-TNF Drugs) (Green Category)

Dr. Pritchard gave the Magellen presentation on Cytokine and CAM Agonists. Cytokines and cell adhesion molecules (CAM) are involved in inflammatory processes throughout the body. These agents are indicated for use in rheumatoid arthritis. Some are indicated for treatment and some are indicated for reducing signs and symptoms. Other uses increase psoriatic arthritis, Crohn's Disease, and ankylosing spondylitis. There are various drug interactions, contraindications, and warnings so the PI should be consulted for information specific to each drug. In August, there were 67 claims: 54% for Enbrel, 42% for Humira, 3% for Cimzia's syringe kit, 1.5% for Simponi. At the last review, a motion

for therapeutic alternatives passed unanimously. The new information is that Orencia is available as a single dose, pre-filled syringe for subcutaneous injection. There was also a change to the PI's boxed warning, which is a safety update regarding opportunistic infections to now include the pathogen names Listeria and Legionella.

DR. CARLSON MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

23. Review Minutes from April 2011 Meeting

With no changes, Dr. Brodsky directed that the April 2011 meeting minutes be adopted as presented.

24. Comments from Committee Members or Chair

Dr. Brodsky welcomed all of the new members to the committee. November 18, 2011, is the next meeting scheduled.

25. Adjourn

Without objection, the meeting adjourned at 10:05 a.m.